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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,842	12/10/2001	Reena Rao	11378.36US01	1838

23552 7590 01/11/2006

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 15, 2005 has been entered.

Claims 1-9 and 11-20 are pending in the application, with claims 11-19 having been previously withdrawn as drawn to a non-elected invention.

Applicant's arguments with regards to the rejection of the claims 1-9 under 35 U.S.C. 112, first paragraph, as introducing new matter into claim 1, have been fully considered but they are not persuasive. Accordingly, claim 1-9 remain rejected under 35 U.S.C. 112, first paragraph, and newly added claim 20 is also being rejected under 35 U.S.C. 112, first paragraph.

Applicant's arguments with regards to the rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over the article entitled "Modification of Vegetable Oils by Lipase Catalyzed Interesterification" by Kaimal et al have been fully considered but they are not persuasive. Accordingly, claims 1-9 remain rejected under 35 U.S.C. 103(a).

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Newly added claim 20 is also being rejected over the Kaimal et al. reference under 35 U.S.C. 103(a).

The claim rejections have been re-written to more completely address Applicant's arguments, and are set forth below.

Claim Rejections - 35 USC § 112

Claims 1-9 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, claim 1 has been amended to recite the limitations of “**about** 46 mol % of omega 6 polyunsaturated fatty acid” and “**about** 17 mol % of Lauric acid.” However, the limitations of “about” 46 mol% and “about” 17 mol% of the recited components are not supported in the originally filed specification and claims. Instead, the table shown on page 9 of the Specification shows the composition of an interesterified coconut oil having 46 mol % of linoleic acid, which is an omega 6 polyunsaturated fatty acid, and 17 mol % of lauric acid. The Specification does not disclose a range that is “about” these measurements, i.e. the Specification does not disclose a range that includes mol % values that are slightly lower than or slightly higher than the recited values, or teach or suggest what such a

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suitable range might be. Thus, while the specification provides support for the narrower species of “46 mol %” and “17 mol %”, it does not provide support for the broader genus of “**about** 46 mol %” and “**about** 17 mol%.” Accordingly, as the ranges of “**about**” 46 mol % and “**about**” 17 mol % are not supported in the originally filed specification, claim 1 is rejected under 35 U.S.C. 112, first paragraph. Claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, as being dependent upon a rejected claim.

Claim 20 is similarly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the phrases “**about** 11 mol% Myristic acid,” “**about** 9 mol % palmitic acid,” “**about** 2 mol% stearic acid” and “**about** 15 mol% oleic acid” are not supported in the originally filed specification and claims, and thus constitute new matter. While the specification provides support for the narrower species of “11 mol % Myristic acid”, “9 mol% palmitic acid”, “2 mol% stearic acid” and “15 mol % oleic acid,” the specification does not disclose or provide any support for the larger genus of mol% values that are included in the range that is “**about**” these values as claimed. Accordingly, claim 20 is rejected under 35 U.S.C. 112, first paragraph for introducing new matter that is not supported by the originally filed Specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 20 are rejected under 35 U.S.C. 103(a) as being obvious over the article entitled "Modification of Vegetable Oils by Lipase Catalyzed Interesterification" by Kaimal et al (of record.)

Kaimal et al. teaches lipase catalyzed interesterification as a means to modify the fatty acid and glyceride content of common vegetable oils to alleviate drawbacks of these oils (see abstract, in particular.) With regards to coconut oil Kaimal et al. teaches that coconut oil is a saturated fat with lauric acid constituting one of the major fatty acids (see paragraph bridging pages 2-3, in particular.) Kaimal et al. teaches that coconut oil is low in linoleic acid, an essential fatty acid (omega 6 polyunsaturated fatty acid), and thus teaches that it is desirable to remove the C-16 and C-18 saturated acids and incorporate linoleic acid in sufficient amounts to provide essential fatty acid requirements and nutritional quality, as well as to provide medium chain fatty acids that are better absorbed and metabolized (see paragraph bridging page 2-3, in particular.) To this end, Kaimal et al. teaches that lipase catalyzed interesterification can be used to modify coconut oil by reducing the higher saturated acids with simultaneous incorporation of medium chain fatty acids and linoleic acid (see page 3, left hand columns first through fifth full paragraphs, in particular.)

Kaimal et al. provide examples of the interesterification of coconut oil to improve the nutritional quality of the oil (see paragraph bridging page 7-8 and page 8, in particular.) Kaimal et al. teaches that medium chain fatty acids such as capric and myristic acid are introduced into the coconut oil to reduce the content of higher saturated acids in the oil (see paragraph bridging pages 7-8 and first full paragraph on page 8, in particular.) Kaimal also teaches that in an attempt to incorporate linoleic acid into coconut oil, the coconut oil was interesterified with a mixture of fatty acids including the capric and myristic acids, as well as safflower oil (see page 8, paragraph bridging right and left hand columns, in particular.) Table 17 lists the contents of the resulting interesterified coconut oil, showing an increased linoleic acid (18:2) content over the non-interesterified oil. Kaimal et al. teaches that the coconut oil product may be suitable as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, first full paragraph in left hand column, in particular.)

Accordingly, Kaimal et al. teaches an interesterified coconut oil comprising fatty acids obtained from triglycerides of safflower oil, namely linoleic acid (an omega 5 polyunsaturated fatty acid), and further teaches that the interesterified oil comprises lauric acid because Kaimal et al. teaches that lauric acid is a major fatty acid constituent of coconut oil (see paragraph bridging pages 2-3, in particular.)

Kaimal et al. does not specifically teach the interesterified coconut oil comprising the recited mol % of omega 6 polyunsaturated fatty acids and lauric acid. However,

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Kaimal et al. clearly teaches that fatty acids such as linoleic acid (via interesterification with safflower oil), capric acid and myristic acid can be incorporated into the oil to provide nutritional benefit and can replace the existing fatty acids, especially long chain saturated acids (see paragraph bridging pages 2-3 and pages 7-8 in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amounts and ratios of safflower oil and/or other fatty acids (such as even linoleic acid) that are combined with the coconut oil in the interesterifying reaction, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

It is respectfully pointed out that instant claims 1-9 and 20 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113. In the instant case, the claimed product is obvious from the prior art, because the prior art product comprises interesterified coconut oil having fatty acids that are obtained from the triglycerides of safflower oil, such as linoleic acid. The product

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thus obtained by the lipase enzyme is deemed to be equivalent to an interesterified coconut oil wherein the fatty acids are obtained from the hydrolysis of triglycerides of safflower oil, as claimed.

Furthermore, it is noted that claim 1 as written reads on interesterifying coconut oil with any of the free fatty acids that are obtained from the hydrolysis of triglycerides of safflower oil, which reads on the interesterification of coconut oil with linoleic acid, a fatty acid that can inherently be obtained in free form from the hydrolysis of triglycerides of safflower oil. Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate linoleic acid into the coconut oil, in an amount and percent by mol as desired, to provide an interesterified coconut oil that is an obvious variant of the product-by-process recited in claim 1. One of ordinary skill in the art would furthermore find it obvious to vary the amount and percent by mol of the linoleic acid incorporated into the coconut oil, for example to arrive at the percent by mol recited in claim 1, with the expectation of providing an interesterified coconut oil having beneficial nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, claim 1 is obvious over the teachings of Kaimal et al.

While it is not being specifically relied on for the present rejection, it is noted that Applicants teach on page 6 of the instant Specification that the method for the hydrolysis of triglycerides of vegetable oils is known in the art.

Claims 2-3 are directed to compositions wherein the lauric acid provides quick energy for critically ill patients, and is nutritionally beneficial in being hypocholesterolemic and hypotriglyceridemic. It is noted that Kaimal et al. teaches that the interesterified coconut oil can be used as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, right hand column, first full paragraph, in particular.) Furthermore, as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the quick energy for critically ill patients and nutritional benefits, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Claims 4 and 6 are directed to compositions wherein the interesterified coconut oil reduces total cholesterol levels in serum by a recited amount, and increases

eicosanoid production in immune compromised patients. It is noted that Kaimal et al. teaches that the interesterified coconut oil can be used as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, right hand column, first full paragraph, in particular.) Furthermore, as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the reduction in serum cholesterol level and increased eicosanoid production, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 5, Kaimal does not specifically teach that a recovery percentage of the interesterified coconut oil, and thus does not specifically teach a recovery percentage that is in the range of 88-92%, as recited in the claim. However, Kaimal et al. does teach several methods of interesterification of the oils, including by batch stirred reaction and packed-bed continuous reaction (see page 3, right hand column, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to select among the methods taught by Kaimal to obtain a desired recovery percentage of the interesterified coconut

oil. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 8, Kaimal et al. teaches an interesterified coconut oil having safflower oil fatty acids and triacylglycerols of coconut oil, as discussed above.

Claim 7 is directed to a composition wherein the interesterified coconut oil has a melting point as claimed and remains a liquid without phase separation. It is noted that as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the melting point and phase separation properties, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 9, it is noted that Kaimal teaches an interesterified coconut oil wherein the starting oil is simply coconut oil, and thus has the n-6 PUFA levels that are as claimed or at least are close to those as claimed, and furthermore teaches that

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linoleic acid can be incorporated into the coconut oil by interesterification, for example via safflower oil, as discussed above. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of linoleic acid and/or safflower oil provided for transesterification with the coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 20, it is noted that Kaimal et al. teaches that capric and myristic fatty acid can be interesterified into the coconut oil (see pages 7-8, in particular), as discussed above. Kaimal et al. also teaches that non-interesterified coconut oil itself has a quantity of capric acid fatty acids (10:0) and myristic fatty acids (14:0) (see Table 17, in particular.) Kaimal et al. further teaches that long chain saturate fatty acids such as palmitic acid and stearic acid, can be removed from the fat and replaced with medium chain length fatty acids during the interesterification process (see paragraph bridging pages 2-3, in particular), and teaches the quantities of palmitic acid (16:0) and stearic acid (18:0) present in the non-interesterified coconut oil (see Table 17, in particular.) Kaimal et al. also teaches that oleic acid (18:1) is present in the non-interesterified coconut oil (see Table 17, in particular), and teaches that oleic acid can be incorporated via interesterification into oils to reduce the content of unwanted fatty

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acids (see page 4, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the fatty acids provided in the interesterified coconut oil, for example by interesterifying with the fatty acids or replacing the fatty acids in the oil with other fatty acids via interesterification, according to the guidance provided by Kaimal et al, to provide an interesterified oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Response to Arguments

Applicant's arguments received November 15, 2005 have been fully considered but they are not persuasive.

With regards to the rejection of the claims under 35 U.S.C. 112, second paragraph, Applicants assert that the deficiencies in the claims have been corrected by the amendment to claim 1. However, the Examiner notes that the amendment has not remedied the deficiencies of the claim, as no support exists in the originally filed specification and claims for the range that are "about" the recited mol %.

Regarding the rejection of the claims under 35 U.S.C 103(a), Applicants argue that the invention as claimed is an improvement over the prior art, particularly in the incorporation of omega 6 polyunsaturated fatty acids into the interesterified coconut oil. However, as discussed above, Kaimal et al. teaches the desirability of incorporating linoleic acid into the coconut oil via interesterification to provide nutritional benefits, and furthermore exemplifies providing the linoleic acid via interesterification with safflower oil. Accordingly, even though Kaimal et al. does not teach the specific mol percentages of linoleic acid as claimed, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of linoleic acid provided in the interesterified coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Applicant's furthermore argue that the product-by-process as claimed is capable of providing an interesterified coconut oil having amounts of caprylic, capric and oleic acid that are other than those specifically exemplified by Kaimal et al. However, as discussed above, Kaimal et al. teaches that the fatty acids in coconut oil can be selectively provided or removed according to the desired nutritional and/or cooking benefits, and teaches caprylic, capric and oleic acid as acids that are present in non-

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interesterified coconut oil, and which additional quantities can optionally be added into the coconut oil via interesterification. Accordingly, even though Kaimal et al. does not teach the specific mol percentages of components as claimed, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the interesterified coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional and/or cooking properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Applicants furthermore argue that Kaimal et al. follows a different method to generate the product than that claimed, namely the lipase-catalyzed interesterification of coconut oil with safflower oil, whereas the instant claims recite interesterification with free fatty acids obtained from hydrolysis of triglycerides. However, Applicants are respectfully reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See

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MPEP 2113. In the instant case, the product-by-process as claimed is obvious over the product of Kaimal et al, as discussed above.

Applicants furthermore argue that Kaimal et al. does not give clear cut evidence that the observed changes are due to lipase catalyzed modification, as opposed to a result of mere dilution with safflower oil to create a blended oil. The Examiner respectfully points out that Kaimal et al. specifically teaches removing C-16 and C-18 saturated acids and incorporating linoleic acid into the fat (see paragraph bridging pages 2-3) and teaches that incorporation of that linoleic acid into the coconut oil was achieved with interesterification of the coconut oil with fatty acids including capric and myristic acid, as well as safflower oil (see page 8, in particular), of which ingredients only safflower oil is a source of linoleic acid. Kaimal et al. further teaches the resulting linoleic acid content of the interesterified coconut oil (see Table 17, in particular.) Accordingly, Kaimal et al. clearly teaches that linoleic acid from the safflower oil is being interesterified into the coconut oil, and does not teach that the safflower oil and coconut oil are merely being blended, as asserted by Applicants.

Conclusion


No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In particular, U.S. Patent No. 5,190,868 to Kokusho et al. teaches a process for the interesterification of fats or oils in which oils such as coconut oil can be interesterified by fatty acids including linoleic acid (linolic acid) (see abstract and column 5, lines 20-50, in particular.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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